



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1774-FN]

Medicare Program; Approval of Request for an Exception to the Prohibition on Expansion of Facility Capacity under the Hospital Ownership and Rural Provider Exceptions to the Physician Self-Referral Prohibition

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces our decision to approve the request from Doctors Hospital at Renaissance, Ltd.'s for an exception to the prohibition on expansion of facility capacity.

DATES: The decision announced in this notice is applicable on December 16, 2022.

ADDRESSES: POH-ExceptionRequests@cms.hhs.gov.

I. Background

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law: (1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship unless the requirements of an applicable exception are satisfied; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for any improperly referred designated health services. A financial relationship may be an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary of the Department of Health and Human Services (the Secretary) the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

Section 1877(d) of the Act sets forth exceptions related to ownership or investment interests held by a physician (or an immediate family member of a physician) in an entity that furnishes designated health services. Section 1877(d)(2) of the Act provides an exception for ownership or investment interests in rural providers (the “rural provider exception”). In order to qualify for the rural provider exception, the designated health services must be furnished in a rural area (as defined in section 1886(d)(2) of the Act) and substantially all the designated health services furnished by the entity must be furnished to individuals residing in a rural area. In addition, in the case where the entity is a hospital, the hospital must meet the requirements of section 1877(i)(1) of the Act no later than September 23, 2011. Section 1877(d)(3) of the Act provides an exception for ownership or investment interests in a hospital located outside of Puerto Rico (the “whole hospital exception”). In order to qualify for the whole hospital exception, the referring physician must be authorized to perform services at the hospital, the ownership or investment interest must be in the hospital itself (and not merely in a subdivision of the hospital), and the hospital must meet the requirements of section 1877(i)(1) of the Act no later than September 23, 2011.

II. Prohibition on Facility Expansion

Section 6001(a)(3) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111-148) amended the rural provider and whole hospital exceptions to provide that a hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but did have a provider agreement in effect on December 31, 2010, the effective date of such provider agreement) (the hospital’s “baseline number of operating rooms, procedure rooms, and beds”). Thus, since March 23, 2010, a physician-owned hospital that seeks to avail itself of either exception is prohibited from expanding the number of operating rooms, procedure rooms, and beds (“facility capacity”) unless it has been granted an exception to the prohibition by the Secretary.

Section 6001(a)(3) of the Affordable Care Act added new section 1877(i)(3)(A)(i) of the Act, which required the Secretary to establish and implement a process for granting exceptions to the prohibition on expansion of facility capacity for hospitals that qualify as an “applicable hospital.” Section 1106 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) amended section 1877(i)(3)(A)(i) of the Act to require the Secretary to establish and implement a process for granting exceptions to the prohibition on expansion of facility capacity for hospitals that qualify as either an “applicable hospital” or a “high Medicaid facility.” These terms are defined at sections 1877(i)(3)(E) and 1877(i)(3)(F) of the Act. The process for requesting an exception to the prohibition on expansion of facility capacity is discussed in section III of this notice.

The requirements for qualifying as an applicable hospital are set forth at § 411.362(c)(2), and the requirements for qualifying as a high Medicaid facility are set forth at § 411.362(c)(3). An “applicable hospital” means a hospital: (1) that is located in a county in which the percentage increase in the population during the most recent 5-year period (as of the date that the hospital submits its request for an exception to the prohibition on expansion of facility capacity) is at least 150 percent of the percentage increase in the population growth of the State in which the hospital is located during that period, as estimated by the Bureau of the Census; (2) whose annual percent of total inpatient admissions under Medicaid is equal to or greater than the average percent with respect to such admissions for all hospitals in the county in which the hospital is located during the most recent 12-month period for which data are available (as of the date that the hospital submits its request for an exception to the prohibition on expansion of facility capacity); (3) that does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries; (4) that is located in a State in which the average bed capacity in the State is less than the national average bed capacity; and (5) that has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is

located. A “high Medicaid facility” means a hospital that: (1) is not the sole hospital in a county; (2) with respect to each of the three most recent 12-month periods for which data are available, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located; and (3) does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries. The regulation at § 411.362(c)(2)(ii) specifies the acceptable data sources for determining whether a hospital qualifies as an applicable hospital, and the regulation at § 411.362(c)(3)(ii) specifies the acceptable data sources for determining whether a hospital qualifies as a high Medicaid facility.

III. Exception Approval Process

In the Calendar Year (CY) 2012 Outpatient Prospective Payment System/Ambulatory Surgical Centers (OPPS/ASC) final rule (76 FR 74121), we published regulations establishing the process for a hospital to request an exception from the prohibition on facility expansion (the “exception process”) at § 411.362(c)(4), the process for obtaining community input related to a hospital’s request at § 411.362(c)(5), and related definitions at § 411.362(a).

In the CY 2015 OPPS/ASC final rule (79 FR 66770), we expanded the permissible data sources on which a hospital may rely to show that it is qualified to request an exception to the prohibition on expansion of facility capacity (that is, that the hospital qualifies as either an applicable hospital or a high Medicaid facility). We also amended the exception process established in the CY 2012 OPPS/ASC final rule to increase the period of time after which an exception request will be deemed complete when an external data source is used by a requesting hospital or in the public comments to determine whether a hospital qualifies as either an applicable hospital or high Medicaid facility. In the CY 2015 OPPS/ASC final rule, we stated that it is possible (if not likely) that, when reviewing an expansion exception request, the Centers for Medicare & Medicaid Services (CMS) would need to verify the data (and other information,

if any) provided by the requesting hospital and any commenters, as well as consider the data in light of the information otherwise available to CMS (79 FR 66995).

In the CY 2021 OPPS/ASC final rule (85 FR 85866), we revised the regulations that set forth the exception process with respect to high Medicaid facilities to remove certain regulatory restrictions that are not included in the Act. As of January 1, 2021, a high Medicaid facility may request an exception to the prohibition on expansion of facility capacity more frequently than once every 2 years; may request to expand its facility capacity beyond 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds; and, if its request is granted, is not restricted to locating approved expansion capacity on the hospital's main campus. An applicable hospital remains subject to the statutory limitation on the frequency of requests for an exception to the prohibition on expansion of facility capacity (no more than once every 2 years); may not request to expand its facility capacity beyond 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds; and, if its request is granted, is restricted to locating approved expansion capacity on the hospital's main campus.

Our regulations at § 411.362(c)(5) require us to solicit community input on the request for an exception by publishing a notice of the request in the **Federal Register**. Individuals and entities in the hospital's community will have 30 days to submit comments on the request. Community input must take the form of written comments and may include documentation demonstrating that the hospital requesting the exception does or does not qualify as an applicable hospital or high Medicaid facility as defined at § 411.362(c)(2) and (3), respectively. In the November 30, 2011 final rule (76 FR 74522), we gave examples of community input, such as documentation demonstrating that the hospital does not satisfy one or more of the data criteria or that the hospital discriminates against beneficiaries of Federal health programs; however, we noted that these were examples only and that we do not restrict the type of community input that may be submitted. If we receive timely comments from the community, we notify the requesting hospital, and the hospital has 30 days after such notice to submit a rebuttal statement

(§ 411.362(c)(5)).

A request for an exception to the facility expansion prohibition is considered complete as follows:

- If the request, any written comments, and any rebuttal statement include only Healthcare Provider Cost Reporting Information System (HCRIS) data, the request is considered complete as of: (1) the end of the 30-day comment period if CMS receives no written comments from the community; or (2) the end of the 30-day rebuttal period if CMS receives written comments from the community, regardless of whether the hospital submitting the request submits a rebuttal statement (§ 411.362(c)(5)(i)).
- If the request, any written comments, or any rebuttal statement include data from an external data source, the request is considered complete no later than: (1) 180 days after the end of the 30-day comment period if CMS receives no written comments from the community; or (2) 180 days after the end of the 30-day rebuttal period if CMS receives written comments from the community, regardless of whether the hospital submitting the request submits a rebuttal statement (§ 411.362(c)(5)(ii)).

If we grant the request for an exception to the prohibition on expansion of facility capacity for a hospital that qualifies as an applicable hospital, the expansion may occur only in facilities on the hospital's main campus and may not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds (§ 411.362(c)(6)). If we grant the request for an exception to the prohibition on expansion of facility capacity for a hospital that qualifies as a high Medicaid facility, these limitations do not apply. The CMS decision to grant or deny a hospital's request for an exception to the prohibition on expansion of facility capacity must be published in the **Federal Register** in accordance with our regulations at § 411.362(c)(7).

IV. Public Response to Notice with Comment Period

On February 9, 2022, we published a notice in the **Federal Register** entitled “Announcement of Request for an Exception to the Prohibition on Expansion of Facility Capacity under the Hospital Ownership and Rural Provider Exceptions to the Physician Self-Referral Prohibition” (87 FR 7471). In the February 9, 2022 notice, we stated that, as permitted by section 1877(i)(3) of the Act and our regulations at § 411.362(c), the following physician-owned hospital requested an exception to the prohibition on expansion of facility capacity:

Name of Facility: Doctors Hospital at Renaissance, Ltd.

Location: 5501 South McColl Road, Edinburg, Texas 78539.

Basis for Exception Request: High Medicaid Facility.

The request that is the subject of this notice is the second request for an exception to the prohibition against expansion of facility capacity that Doctors Hospital at Renaissance, Ltd. (DHR) has submitted to CMS. In the September 17, 2015 **Federal Register** notice (80 FR 55851), we published our decision granting DHR’s request to add a total of 551 operating rooms, procedure rooms, and beds for which it is licensed, permitting an increase in DHR’s facility capacity to 200 percent of its baseline number of operating rooms, procedure rooms, and beds (the 2014 Request). DHR qualified as an applicable hospital at the time it submitted its 2014 Request, which occurred prior to the regulatory revisions that became effective on January 1, 2021. As stated above, the January 1, 2021 regulatory revisions permit a hospital that qualifies as a high Medicaid facility to: (1) request an exception to the prohibition on expansion of facility capacity more frequently than once every 2 years; and (2) request to expand its facility capacity beyond 200 percent of the hospital’s baseline number of operating rooms, procedure rooms, and beds. From September 11, 2015 (the effective date of our decision to grant the 2014 Request) until January 1, 2021, DHR was prohibited from submitting a second request for an exception to the prohibition against expansion of facility capacity under section 1877(i)(3)(B) of the Act and § 411.362(c)(1) (as then in effect). DHR submitted the request that is the subject of this notice (the 2021 Request) on July 21, 2021.

During the 30-day public comment period, we received 14 public comments through www.regulations.gov. Twelve comments supported CMS approving DHR's 2021 Request for an exception to the prohibition against expansion of facility capacity; two comments opposed CMS approving the request. The comments in opposition to CMS approving the 2021 Request did not challenge DHR's qualification as a high Medicaid facility in Hidalgo County, Texas. Rather, the commenters asserted that, even if DHR qualifies as a high Medicaid facility, CMS has authority to deny the request and, to be consistent with the statutory purpose of allowing limited expansion of grandfathered physician-owned hospitals, which focuses on the need for additional facility capacity and beneficiary interests in the community in which the requesting hospital is located, CMS should deny the request. One of these commenters asserted that, given DHR's publicly-stated plans to expand outside Hidalgo County, Texas, granting the 2021 Request would result in the establishment of a new physician-owned hospital in contravention of section 1877(i) of the Act.

On April 22, 2022, DHR filed a rebuttal statement in response to the comments that opposed CMS granting its 2021 Request for an exception to the prohibition against expansion of facility capacity. Among other things, DHR asserted that, because it qualifies as a high Medicaid facility, CMS must grant its 2021 Request for an exception to the prohibition against expansion of facility capacity.

V. Decision

DHR submitted the information, data, and certifications specified at § 411.362(c)(4). This notice announces our decision with respect to DHR's 2021 Request for an exception to the prohibition against expansion of facility capacity.

A. Qualification as a High Medicaid Facility

In order to make a request with respect to which CMS may issue a decision, a hospital must qualify as an applicable hospital or a high Medicaid facility. As of the date of its 2021 Request, DHR was located in Hidalgo County, Texas. We determined that, on the date the

2021 Request was submitted, DHR qualified as a high Medicaid facility in Hidalgo County, Texas, for the following reasons:

- DHR is not the sole hospital in Hidalgo County, Texas;
- With respect to each of the three most recent 12-month periods for which data were available as of the date the hospital submitted its 2021 Request, DHR had an annual percent of total inpatient admissions under Medicaid that was estimated to be greater than such percent with respect to such admissions for any other hospital located in Hidalgo County, Texas; and
- DHR certified that it does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

B. Decision Regarding the 2021 Request for an Exception to the Prohibition on Facility Expansion

After reviewing DHR's 2021 Request, the public comments, and DHR's rebuttal statement, we are granting DHR's 2021 Request for an exception to the prohibition against expansion of facility capacity. Our decision grants DHR's 2021 Request to add a total of 551 operating rooms, procedure rooms, and beds. Under the regulations in effect as of the date that the 2021 Request was submitted, the location of the expansion is not limited to facilities on the hospital's main campus, and may result in the number of operating rooms, procedure rooms, and beds for which DHR is licensed exceeding 200 percent of its baseline number of operating rooms, procedure rooms, and beds.

CMS makes no determination as to whether, following expansion, any financial relationships between DHR and its physician owners would satisfy any other requirement of the whole hospital or rural hospital exceptions.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting,

recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: December 15, 2022.

Lynette Wilson,

Federal Register Liaison,

Center for Medicare & Medicaid Services.